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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/288,837	04/08/99	MACDONALD G	5470-238

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EXAMINER	
BRUMBACK, B	
ART UNIT	**PAPER NUMBER**
1642	

DATE MAILED: 08/28/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Advisory Action

Application No.	Applicant(s)
09/288,837	MacDonald et al.
Examiner	**Art Unit**
Brenda Brumback	1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED *Jul 30, 2001* FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid the abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

THE PERIOD FOR REPLY [check only a) or b)]

a) ☒ The period for reply expires *4* months from the mailing date of the final rejection.

b) ☐ In view of the early submission of the proposed reply (within two months as set forth in MPEP § 706.07 (f)), the period for reply expires on the mailing date of this Advisory Action, OR continues to run from the mailing date of the final rejection, whichever is later. In no event, however, will the statutory period for the reply expire later than SIX MONTHS from the mailing date of the final rejection.

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☒ The proposed amendment(s) will be entered upon the timely submission of a Notice of Appeal and Appeal Brief with requisite fees.

3. ☐ The proposed amendment(s) will not be entered because:

   (a) ☐ they raise new issues that would require further consideration and/or search. (See NOTE below);

   (b) ☐ they raise the issue of new matter. (See NOTE below);

   (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

   (d) ☐ they present additional claims without cancelling a corresponding number of finally rejected claims.

   NOTE: _____

4. ☐ Applicant's reply has overcome the following rejection(s):

5. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment cancelling the non-allowable claim(s).

6. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because:
   See attached.

7. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

8. ☒ For purposes of Appeal, the status of the claim(s) is as follows (see attached written explanation, if any):

   Claim(s) allowed: _____

   Claim(s) objected to: _____

   Claim(s) rejected: *84, 85, 89-93, and 96-102*

9. ☐ The proposed drawing correction filed on _____ a) ☐ has b) ☐ has not been approved by the Examiner.

10. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ .

11. ☐ Other:

DETAILED ACTION

Attachment to Advisory Action

Claim Rejections - 35 USC § 103

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. Claims 84, 85, and 90-93 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Johnston et al. in view of Falo Jr. et al. Additionally, new claims 95-102 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johnston et al. in view of Falo Jr. et al. for the reasons of record for claims 84, 85, and 90-93. Applicant's arguments and the Olmsted Declaration, have been fully considered but they are not persuasive for the following reasons.

Applicant argues that the references themselves do not provide a motivation or suggestion to combine. However, the motivation to combine is found in the references as follows. Johnston teaches that VEE virus particles (an alphavirus) can be constructed to comprise a heterologous RNA segment encoding an antigen and that the particle constructs effectively elicit protective B and T-cell immunity against the heterologous antigen when administered to a subject (see the abstract and page 1, line 15, through page 2, line 6, and page 2, line 33, through page 3, line 2). Falo teaches prophylactic and therapeutic anti-tumor immunization based on cross-priming a mammalian host to natural MHC class 1 restricted tumor antigens with an "artificial" tumor

antigen, such as a tumor rejection antigen (abstract and column 4, lines 22-31). Falo teaches that tumor cells modified to present the tumor rejection antigen on the cell surface focus the immune response against the host tumor cells in a manner sufficient to stimulate CTL-mediated immunity to multiple, additional, undefined natural tumor antigens present on unmodified host tumor cells. One of ordinary skill in the art at the time the invention would have found it *prima facie* obvious to have incorporated the tumor rejection antigen disclosed by Falo into the VEE particles taught by Johnston in order to formulate a composition that could be used to elicit a prophylactic or therapeutic immunogenic response against host tumor cells.

Applicant argues that even if the teachings of the cited references are combined, one would not arrive at the claimed invention because the present claims recite a "native cancer antigen" and neither Johnston not Falo teach a native cancer antigen. Applicant further argues that Falo teaches an artificial tumor antigen. Applicant's argument is not persuasive, however, for the following reason. Applicant's disclosure teaches a native cancer antigen as a "naturally occurring" cancer antigen (see page 7, line 6, and page 12, lines 22-23) and as any cancer antigen that is expressed on the surface of a cancer cell. Applicant recites specific embodiments of native cancer antigens as *HER2*, MAGE-1, and MAGE-3, among others (page 17, line 31, through page 18, line 4). Falo teaches the very same antigens as tumor rejection antigens or as "artificial" target antigens (column 4, lines 22-31). This, absent some evidence to the contrary the "artificial" cancer antigens disclosed by Falo are identical to the "native" cancer antigens of applicant's disclosure. Applicant's assertion that Falo "is intending to use these 'tumor rejection

antigens' as artificial tumor antigens, presumably to produce an immune response against tumors that do not express these antigens" is noted; however, the examiner can find no such teaching in Falo.

The Olmsted Declaration has been considered; however, once again, the "native" cancer antigen discussed in the Declaration is the HER2/neu antigen, which is the same antigen as one of the tumor rejection or "artificial" cancer antigens disclosed by Falo.

Applicant argument that it would have been unexpected that a composition comprising an alphavirus vector encoding a native cancer antigen could be directly administered to an animal to effectively provide protection against cancer because Falo describes a two-part vaccination strategy is noted; however, its relevance is not completely understood, as applicant's claims are drawn to a composition, not to a method. It would seem that applicant is arguing that the references fail to show certain features of applicant's invention; however, it is noted that the features upon which applicant relies (i.e., features related to vaccination strategy) are not recited in the rejected claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda Brumback whose telephone number is (703) 306-3220. If the examiner can not be reached, inquiries can be directed to Supervisory Patent Examiner Anthony Caputa whose telephone number is (703) 308-3995. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone

number is (703) 308-0196. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Examiner Brenda Brumback, Art Unit 1642 and should be marked "OFFICIAL" for entry into prosecution history or "DRAFT" for consideration by the examiner without entry. The Art Unit 1642 FAX telephone number is (703)-305-3014. FAX machines will be available to receive transmissions 24 hours a day. In compliance with 1096 OG 30, the filing date accorded to each OFFICIAL fax transmission will be determined by the FAX machine's stamped date found on the last page of the transmission, unless that date is a Saturday, Sunday or Federal Holiday with the District of Columbia, in which case the OFFICIAL date of receipt will be the next business day.

Brenda Brumback
August 24, 2001

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